

DISCUSSION OF THE AMENDMENT

Claim 16 has been amended to correct an inadvertent omission in the definition of R^{10} . In the previous amendment, it was stated that new claims were based on, *inter alia*, Claim 2. Claim 2 recited, *inter alia*, that if R^3 is NR^7COR^{10} , R^{10} is R^8 . Thus, this limitation has been added, as well as correcting " NR^7COR^8 " to " NR^7COR^{10} ".

Claim 25 has been amended to correct an inadvertent error in the definition of "Het", which is a 5- or 6-membered non-aromatic heterocycle, as supported by, for example, original Claim 1 and page 6, line 11 of the specification.

New Claim 38 has been added, which limits R^{10} and B of Claim 25 to, in effect, nonheterocyclic groups.

No new matter is believed to have been added by the above amendment. Claims 16-38 are now pending in the application.

REMARKS

Applicants thank the Examiner for the courtesy extended to Applicants' attorney during the interview held May 29, 2008, in the above-identified application. During the interview, the Examiner indicated that the rejection identified under Ground (B) below had been withdrawn, as reflected by the corresponding Interview Summary.

Ground (A)

Claims 16-37 stand rejected under 35 U.S.C. § 103(a) as unpatentable over "the combined teachings of" US 6,432,988 (Laufer et al).¹ That rejection is untenable and should not be sustained.

The Advisory Action indicates that this rejection is withdrawn with respect to the elected compounds only. The Examiner has characterized the scope of elected compounds as those wherein R¹⁰ is tetrahydropyran or nonheterocyclic, and B is nonheterocyclic. Accordingly, it is respectfully requested that this rejection be withdrawn.

Since the elected compounds are now allowable, in view of the terminal disclaimer submitted, discussed *infra*, it is incumbent on the Examiner to expand her search and examination to include an expanded definition of R¹⁰ and B.

Note further that R¹⁰ in independent Claim 16 is not inclusive of heterocyclic compounds, and there is no B in Claim 16. In addition, Claims 27 and 28 are not inclusive of R¹⁰ or B containing a heterocyclic group. Thus, Claim 16 and all claims dependent thereon, and Claims 27 and 28, are now allowable.

¹ In a telephone conversation with undersigned counsel on February 19, 2008, the Examiner confirmed that the rejection is over Laufer et al alone.

Ground (B)

Claims 16-34 stand rejected on the ground of nonstatutory obviousness-type double patenting over Claims 1-8, 10, 13 and 14 of Laufer et al. As discussed above, the Examiner has withdrawn this rejection.

Ground (C)

Claims 16-34 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting over Claims 1-17 of copending Application No. 10/514,911 (copending application). **Submitted herewith** is a terminal disclaimer over the copending application. Accordingly, it is respectfully requested that this rejection be withdrawn.

Ground (D)

Claims 24, 34, 36 and 37 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. That rejection is untenable and should not be sustained.

It is respectfully submitted that the data described in the specification at page 29 herein in Table 1 are based on well-established *in vitro* tests for predicting activity against inflammatory disorders in which TNF- α and IL- β are involved, such as rheumatoid arthritis. While the Examiner purports to list the so-called *Wands* factors, nevertheless, the Examiner has not convincingly indicated why the results in said Table, or the description generally in the specification, would not enable a person skilled in the art to treat inflammatory disorders of the type recited in the claims.

While inflammatory disorders such as rheumatoid arthritis are described as treated by the present invention by immunomodulating and/or cytokine-releasing-inhibiting action, and the Examiner finds that current treatments of rheumatoid arthritis are inadequate and that the

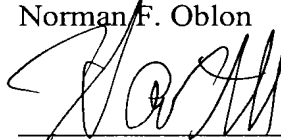
art recognizes that specific anti-rheumatic drugs do not inhibit all cytokines and the mechanisms of action are unclear, nevertheless, it is the Examiner's burden to show that the presently-disclosed *in vitro* data would not be accepted by persons skilled in the art as indicative of *in vivo* behavior. The Examiner, in effect, requires *in vivo* data, which is not required by current case precedent.

For all the above reasons, it is respectfully requested that this rejection be withdrawn.

Applicants respectfully submit that compounds and methods drawn to the elected species are now allowable. All rejections of claims drawn to the compounds have been overcome. Under proper PTO practice, the Examiner is required to expand her search and examination. In the absence of further grounds of rejection, the Examiner is respectfully requested to pass this application to issue with all pending claims.

Respectfully submitted,

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